

AFFIDAVIT OF BRUCE ROSENZWEIG, M.D.

STATE OF ILLINOIS

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COUNTY OF COOK

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1. I, Bruce Rosenzweig, M.D., am over the age of 18 and fully competent to testify to the matters stated herein.

2. I have personal knowledge of the facts stated herein.

3. My knowledge of Randomized Controlled Trials (“RCTs”) is informed not only by having reviewed large numbers of them, but also by personal participation in them.

4. I was involved in the development of a new medical device, an Amnio-infusion catheter. As part of that process, I helped to design an RCT to test placing the catheter into the uterus versus placing a single sham catheter. Once we started inventing the double lumen catheter, we considered different embodiments to determine which was most effective.

5. I worked with EMPI on developing and testing the Innova electrical simulator to treat SUI, and helped to design an RCT to test it. The RCT tested using a sham versus using an active simulator placed in the vagina. I was on the scientific advisory board of the company, so I was not an investigator, but I did help to design the RCT.

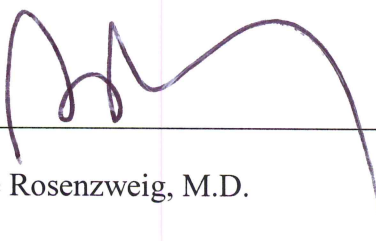
6. I was an investigator for an RCT involving the Lea Shield and Fem cap, which were both cervical cap contraceptives. They required a prescription, and the trial was designed to determine the appropriate size to achieve efficacy and to gain clearance from the FDA to sell the devices over the counter.

7. As I have discussed on many occasions, long-term clinical trials provide more reliable information about safety and efficacy than do short-term trials. However, the value of shorter-term trials is greater in evaluating efficacy than in evaluating safety.

8. For instance, the three-year Okulu study showing that using Ultrapro mesh to cure SUI is effective is valuable information because if the sling were ineffective, it would not cure SUI for that period of time. However, mesh complications often do not manifest for several years, so the length of a study is particularly important with regard to safety.

FURTHER, affiant sayeth naught.

In witness whereof, I have affixed my signature this 9th day of May, 2016.



Bruce Rosenzweig, M.D.

Subscribed and sworn to before me, this 9th day of May, 2016.



NOTARY PUBLIC

My Commission Expires:

8/25/17

